IRIS Public Stakeholder Meeting
Unanswered webinar questions

Pamela Miller, Alaska Community Action on Toxics [first question was answered]**:** The importance of the IRIS program for public health cannot be overstated and it is critical to have an easily trackable system for the public to evaluate progress and efficacy. EPA's primary mission is to protect health and the environment. As noted by speaker Richard Denison, if IRIS assessments are delayed as we have seen in the past, people will continue to suffer unnecessary and harmful illnesses that should be preventable. We think that it is so incredibly important to have accurate, unbiased, and timely assessments of chemical hazards in order to prevent unnecessary illnesses that include birth defects, cancers, adverse reproductive and other health outcomes that we see in our communities. This is not an abstract issue for workers and communities who experience unnecessary and harmful exposures.

Ansje Miller, Center for Environmental Health: [first question was answered] How can those of us on the webinar who cannot regularly come to DC stay engaged in this process? Re: how to engage more stakeholders in IRIS… identify communities that would be vulnerable to exposures to the chemical undergoing assessment and outreach to organizations that represent and organize within those communities. Webinars and meetings in regional offices would be helpful. But we shouldn't have more meetings that would slow the process.

Craig McCormack, Washington Department of Ecology [first question was answered]**:** Weight of evidence approaches implies scientific judgments to be made during scientific evaluations, reconciling prudent public health and environmental policies with ACC's reproducibility criterion may not be able to be done or done in a timely manner. Please comment.
Craig: How does EPA intend to prioritize chemicals that need IRIS assessments?

Amy D. Kyle, University of California Berkeley School of Public Health [first question was answered]: IRIS has largely focused on producing metrics that are useful for "old school" risk assessments such as those developed for regulation of major chemicals. Is EPA considering any more nimble process to generate metrics that could be used to COMPARE chemicals such as through alternative assessments? These are needed in a variety of contexts including but not limited to EPA's "design for environment" program, which currently has to generate conclusions based partly on questionable metrics.

David Szabo, FDA: Directed to Vince, Ken and/or Linda. IRIS should be applauded for their progress on improving positive stakeholder involvement. Question: In keeping with systematic reviews, focusing on the evaluation of study quality, are there any guidelines/criteria used for the evaluation of study quality? If so, are the guidelines/criteria available for viewing? If there are no formal criteria/guidelines being used, are there efforts at a minimum to develop such a criteria list?

Roberta Grant, Texas Commission on Environmental Equality: How many IRIS toxicologists/chemical risk assessors are in the program and how many work on each chemical (i.e., do you have adequate staff)?

Craig Selover, Masco Corporation: given the concern about endless studies to generate more information, are there any rules or guidance regarding things like Mode of Action that should be applied to determine what studies qualify to be included in the IRIS database?

Stephenie Hendricks, Coming Clean: During the Bush administration there was a gag order put on EPA scientists to talk to the public. Is this still in effect and how free are EPA scientists to voice their concerns about industry influence on environmental health protections regulations such a IRIS? Also, will long term neurotoxic health impacts be included and expanded in IRIS evaluations?

Desmond Bannon, DOD: IRIS values ultimately rest on toxicity studies modified by default factors. Weak studies with blind application of default factors results in promulgated values that have low credibility with many stakeholders. How can EPA avoid this and raise credibility in the IRIS values?

Frank Speizer, Harvard University: Underlying much of the problem in the IRIS program is that it sorely underfunded. There needs to be a development of staff personnel who are funded appropriately to do proper risk assessment of existing peer review literature. By limiting the database to peer review literature much of the conflict of interest (COI) and "lack of trust" may be handled by journal editors who have become more concerned about assessing these COI. Too often the input from the "interested stakeholders" is not peer reviewed, and often is biased. If we were to require that the data base be peer reviewed it should help industry provide the incentives to their own scientists to engage in the scientific process, rather than appearing as simply critics of efforts made by the constituted scientific vetted panels EPA employs to review the staffs work. I do not believe that expanding the committee beyond their current representative sizes will help in shortening the review process.

Eileen Murphy, Rutgers University: I am concerned about integrating the opportunity for public and stakeholder comment with the peer review process. They are separate issues. Peer review is a rigorous technical review of the IRIS document, whereas stakeholder/public review can range from technical comments to policy questions. It is inappropriate for the external peer reviewers of IRIS documents to address stakeholder/public comments during their peer review. I would be interested in hearing the rationale for combing these two types of reviews.

Penny Fenner-Crisp, Consultant & EPA retiree: Upwards of 40% of the substances currently on IRIS are there by virtue of their introduction into the environment as pesticides registered by OPP. Most of the IRIS values were generated in the 1980's (mostly by me, Mike Dourson and Reto Engler before the RfD Committee was established). The mandates of FQPA have resulted

in a reevaluation of these chemicals either in the re-registration or registration renewal programs. These reassessments now render many of the IRIS values out of date. The one-off links to OPP's RED/IREDs. etc was somewhat useful for a time, but, since then, even some of OPP's re-assessments have undergone further changes. In order to improve the credibility of the IRIS database as a whole, at a minimum, the outdated IRIS summaries for these chemicals should be removed from the database. Other options include replacing the IRIS values with OPP's or removing the chemicals entirely from the IRIS database, challenging OPP to create its own.

Jacqueline Patterson, Toxicology Excellence for Risk Assessment: My name is Jacqueline Patterson and I manage a non-profit independent peer review program for TERA. I want to thank EPA for today's session and the opportunity to hear directly from EPA and from the wide variety of stakeholders on important issues and developments with IRIS. I am very pleased that EPA is committed to improving IRIS peer review. High-quality, independent peer review is essential to insure IRIS assessments are of excellent quality and are credible. In particular I encourage EPA to make sure that the peer review panels include experts with sufficient experience in risk assessment. The IRIS assessments often involve complex and sometimes conflicting data; multiple experts from the key disciplines are needed who can discuss and interpret the data in a risk assessment context. Peer review panels should be constructed so that robust discussions are possible and controversial issues are fully addressed by scientists with different opinions and perspectives.

Johanna Congleton, Environmental Working Group: Does the EPA IRIS program plan on increasing the role of biomonitoring data, as recommended by the National Academies of Science in "Science and Decisions" (2009)? If so, are there specific strategies under discussion to do so?

Katie Huffling, Alliance of Nurses for Healthy Environments: Nurses, such as myself, and other members of the public health community rely on IRIS assessments in our health care practices. When an assessment is delayed, it translates into increased incidence of illness, even death.

Jerry Poje, Society for Occupational and Environmental Health: Even the impressive 450 participants on today's forum and webinar audience is but a small portion of likely public interest, government and industry participants with IRIS products. What's the likelihood of several smaller locality and state model public engagement projects over the next two years? To hone a more effective public engagement model will require many different attempts at public trust building with locally defined chemical hazards and exposures.

Steven DeSantis, NYSDEC: The EPA's NESHAP program uses IRIS in its Risk and Technology Review Program. Does IRIS staff plan to establish acceptable short-term health effect concentration values., 1-hour or 8 -hour. In previous NESHAP assessments EPA used accidental release concentration values (AEGL) for short-term assessments and these values are not appropriate.

Paula Johnson, University of California at San Francisco – Program on Reproductive Health and the Environment: The issue of "scoring" in systematic reviews has come up several times during this discussion. This is an example of an area where consulting with experts in systematic reviews (such as Cochrane Collaborative or GRADE) would be very useful. Quality scoring, while originally popular for systematic reviews, has evolved out of practice, as empirical evidence found that it was not a fully systematic approach. The GRADE approach is favored in the clinical science arena and can be usefully adopted in translating evidence in the environmental health sciences where animal experimental data and human observational studies are reviewed. Additionally, GRADE is a transparent approach that where judgments are documented during the review process.

Mike Schade, CHEJ: A classic example of how a chemical assessment has been delayed for many, many years, has been dioxin. EPA's dioxin assessment was reviewed by multiple SAB peer review panels, and time after time, industry only asked for more delays and more reviews, meanwhile vulnerable populations continued to be exposed to potentially harmful levels of dioxin. We were very pleased that EPA, after nearly 30 years, finalized its IRIS noncancer assessment for dioxin earlier this year. However at the same time, EPA has still not finished the dioxin cancer assessment. It has been over one year since the SAB completed its dioxin review, and nine months since EPA finalized the noncancer assessment – what is the status and timeframe for completing EPA's dioxin cancer assessment? How much longer will we have to wait? We've been waiting for nearly 30 years already. Thank you.

Steve Risotto, ACC: Question for Ken Olden - In discussions with the NAS committee on perchloroethylene, NCEA staff indicated that they feel that their objective is to find the health end point that generates the lowest (most conservative) risk value regardless of whether that end point is relevant to human health assessment. In your mind, is that the appropriate role for the IRIS program?